

## **REMARKS**

Applicants respectfully request that prior to further substantive examination the foregoing amendments and the following remarks be made of record in the instant case.

### **I. Status of the Claims**

Claims 14-57 are pending in the instant application and stand variously rejected under 35 U.S.C. §112, first paragraph for allegedly lacking of enablement and/or written description, under 35 U.S.C. §112, second paragraph as assertedly being indefinite for failing to particularly point out and distinctly claim the invention, and under the judicially created doctrine of obviousness-type double patenting. Applicants respectfully traverse the rejections and request reconsideration in light of the above amendments and the following remarks.

Certain of the claims have been amended merely to revise the language of the claims for the purposes of consistency and clarity. The amendments to the claims directed to dosage ranges (e.g., claims 24, 34, 35, 44, and 45) are made to incorporate dosage ranges that are discussed in the specification. Such doses are supported e.g., at page 33, lines 10-15.

### **II. Initial Remarks Regarding Telephone Interview with Examiner**

Applicants thank Examiner Rao for the courtesy afforded to the undersigned representative during the telephone conference on Monday March 15, 2004. At that interview, the Examiner and the undersigned representative discussed the underlying rejections of the claims presented above. It was determined that an amendment to the claims which removed language directed to "mutants" should overcome the outstanding rejections under 35 U.S.C. §112, first paragraph for lack of enablement and lack of written description.

As such, and in accordance with the telephone interview, Applicants have amended claims 14, 29 and 39 to remove all recitations of "mutants" of SEQ ID NO:2. These amendments are made without prejudice to Applicants rights to pursue the subject matter of the original scope in continuing applications. With the amendments to the present case however, Applicants believe that claims 14-57 are in condition for allowance, seeing as the

only other rejection of these claims has been addressed by an amendment to claim 26 (see below).

New claims 58, 59 and 60 are merely provided to reiterate subject matter that has been indicated by the Examiner in the office action as enabled and described. For example, these new claims are directed to subject matter supported by the specification as filed and directed to methods of treating subjects in need of such treatment with compositions that comprise  $\alpha$ -L iduronidase or biologically active fragments thereof that are 99% or greater purity (e.g., 99.9% purity). Should the Examiner wish to discuss the introduction of these new claims, Applicants respectfully request a telephone conference with the undersigned representative at the Examiner's convenience.

**III. Rejection of Claim 26 under 35 U.S.C. §112, second paragraph should be withdrawn**

Claim 26 was rejected under 35 U.S.C. §112, second paragraph as assertedly being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants inadvertently omitted a response to this rejection in the previous communication and redress that omission below.

Claim 26 was rejected as allegedly being indefinite because the metes and bounds of the phrase "reduces lysosomal storage" are not clear. Applicants submit that those skilled in the art would understand that, as this therapy is intended to alleviate the symptoms of lysosomal storage disease, the term "reduces lysosomal storage" refers to storage of those moieties that are deleterious in such a disease. However, in order to expedite prosecution and further clarify, Applicants have amended claim 26 to recite:

The method of claim 14 wherein said treatment with human recombinant  $\alpha$ -L-iduronidase reduces lysosomal storage of glycosaminoglycans in the tissue of said human subject caused all or in part by said deficiency in  $\alpha$ -L-iduronidase.

Applicants believe that the above amendment and comments address all of the rejections based on 35 U.S.C. §112, second paragraph and request that the rejections be withdrawn in light of these comments.

**IV. Rejection under 35 U.S.C. §112, First Paragraph for Lack of Enablement and Lack of Written Description Should be Withdrawn**

The Applicants discussed the rejections of claims 14-57 under U.S.C. §112, first paragraph for lack of enablement and lack of written description with the Examiner on Monday March 15, 2004 in a telephone interview. Applicants now understand that the claims were rejected for recitation of a method of treatment using greater than "mutants" of SEQ ID NO:2. Applicants have amended the claims to remove recitation of mutants language and therefore believe that the rejections under 35 U.S.C. §112, first paragraph for lack of enablement and lack of written description have now been overcome. Applicants discussed these amendments with Examiner Rao on March 15, 2004, and believe that these amendments overcome the rejections. Applicants respectfully request reconsideration of the claims for allowance.

**V. Double Patenting Rejection.**

Claims 14-57 were rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,585,971. It is the Examiner's position that since both the instant application and the claims of the 6,585,971 are directed to methods of treating using α-L-iduronidase, the claims of the instant application may not be considered patentably distinct over each other.

Applicants thank the Examiner for the reminder regarding the maintained rejection and for holding the rejection in abeyance. As the filing of a terminal disclaimer will impact the claims of the instant application and as yet the finalized allowed set has not been indicated by the Examiner, any arguments Applicants provide at the instant juncture may be premature. The instant response is being filed prior to the expiration of two months from the mailing date of the final office action and as such, expect to receive an advisory action in due course. If that action advises that the claims as presented above are in condition for allowance but for the double-patenting issue, Applicants will immediately furnish a terminal disclaimer.

Thus again, Applicants respectfully request the Examiner's forbearance and

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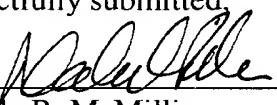
request that this rejection be held in abeyance until such a time as when allowable subject matter is indicated in order to allow Applicants the opportunity to provide a complete but not unduly limiting response. The Examiner's discretion in this matter is respectfully solicited. In the event that the Examiner wishes to discuss this point further, Applicants respectfully invite the Examiner to contact the undersigned representative.

#### **VI. Conclusions**

Applicants believe that all of the rejections have been overcome and the claims of the instant application are now in condition for allowance and request an early indication of such a favorable disposition of the case. The Examiner is invited to contact the undersigned with any questions, comments or suggestions relating to the referenced patent application.

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Respectfully submitted,

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